

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison the effectiveness of lifestyle modification interventions (nutrition and physical activity) in comparison with lifestyle education on nutritional behaviors, physical activity, anthropometric measurements, fasting blood sugar and serum lipid profile in the adults aged 40-60 years

Protocol summary

Registration timing: **prospective**

Summary

The aim of this study is to evaluate the effectiveness of nutrition and physical activity interventions in comparison with education in the population of 40- 60 years old of Amirkola; which will be conducted with random sampling of participants referring to the health center of Amirkola. Enrolled participants will be allocated randomly in the three groups: highly-intensive intervention group, low- intensive intervention group and education group. The sample size is 300. Highly-intensive intervention includes weekly group-training about nutrition and physical activity, individualized nutrition counseling, providing educational materials and weekly free aerobic exercises. Low- intensive intervention includes weekly group-training about nutrition, individualized nutrition counseling and providing educational materials. The third group (control group) will not participate in weekly group-training classes and will receive only educational packages related to the study. Lifestyle status (based on Health-Promoting Life Style Profile questionnaire), nutritional and physical activity behaviors (based on Food Recall questionnaire and the Iranian version of International Physical Activity Questionnaire), besides body mass index, waist, neck, buttock and arm circumferences, body fat, blood pressure, fasting blood glucose and serum lipids will be examined before and after the intervention.

Last update:

Update count: **0**

Registration date

2016-02-05, 1394/11/16

Registrant information

Name

Simin Mouodi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 0624

Email address

s.mouodi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of lifestyle modification

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015070423055N1**

Registration date: **2016-02-05, 1394/11/16**

interventions (nutrition and physical activity) in comparison with lifestyle education on nutritional behaviors, physical activity, anthropometric measurements, fasting blood sugar and serum lipid profile in the adults aged 40-60 years

Public title

Comparison the effectiveness of lifestyle modification interventions

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion Criteria: Age 40-60 years; Living in Amirkola Babol; Desire to participate in the study, fill out and sign the informed consent form of the research Exclusion Criteria: Unable to read and write; Pregnancy or child breast feeding; Severe physical or mental disease which make them disable; Probable migration from Amirkola in 10 months

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization in study population will be performed with random allocation of subjects in the age group of 40- 60 years old in the three groups by random numbers table.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz Avenue, Babol

City

Babol

Postal code

4136747176

Approval date

2015-06-02, 1394/03/12

Ethics committee reference number

mubabol.rec.1394.45

Health conditions studied**1****Description of health condition studied**

Life-style (Factors influencing health status and contact with health services)

ICD-10 code

Z40,Z41,Z4

ICD-10 code description

Persons encountering health services for specific procedures and health care

Primary outcomes**1****Description**

Life style status

Timepoint

Before (0 week) and after the intervention (16th week)

Method of measurement

HPLP-II questionnaire (Health-Promoting Life Style Profile-II)

2**Description**

Main dietary pattern

Timepoint

Before (0 week) and after the intervention (16th week)

Method of measurement

Food Recall Questionnaire

3**Description**

Physical activity status

Timepoint

Before (0 week) and after the intervention (16th week)

Method of measurement

IPAQ:International Physical Activity Questionnaire

Secondary outcomes**1****Description**

Anthropometric measures

Timepoint

Before (0 week) and after the intervention (16 th week)

Method of measurement

Physical examination

2

Description

Blood pressure

Timepoint

Before (0 week) and after the intervention (16 th week)

Method of measurement

Physical examination

3

Description

Fasting blood glucose

Timepoint

Before (0 week) and after the intervention (16 th week)

Method of measurement

Blood sample

4

Description

Serum lipid profile

Timepoint

Before (0 week) and after the intervention (16 th week)

Method of measurement

Blood sample

Intervention groups

1

Description

Intervention group 1: For 4 months (16 weeks), weekly group training about nutrition and physical activity, individualized nutrition counseling, providing educational materials and weekly free aerobic exercises. The content of nutrition classes is adapted from nutritional principles which Ministry of Health and Medical Education of Iran has released. The trainer is an expert nutritionist. The duration of each class is 45 minutes, classes will be taken as group discussion and approximate number of participants is 25-30 persons.

Category

Lifestyle

2

Description

Intervention group 2: For 16 weeks, weekly group training about nutrition and physical activity, individualized nutrition counseling and providing educational materials.

Category

Lifestyle

3

Description

Control group: Only educational package included booklet, CD, pamphlet and papers about lifestyle especially improving nutrition and physical activity.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

population lab of Amirkola

Full name of responsible person

Seyed Reza Hosseini

Street address

Research center, Amirkola

City

Amirkola

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Babol University of Medical Sciences

Full name of responsible person

Ali Akbar Moghadamnia

Street address

Ganjafrooz Avenue, Babol

City

Babol

Grant name

دانشگاه علوم پزشکی و خدمات بهداشتی درمانی بابل

Grant code / Reference number

2786 research code

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Simin Mouodi

Position

MD, MPH

Other areas of specialty/work

Street address

Ganjafrooz Avenue, Babol University of Medical

Sciences, Babol

City

Babol

Postal code

4136747176

Phone

+98 11 3219 0624

Fax

+98 11 3219 0624

Email

dr.mouodi@gmail.com

Web page address

mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyed Reza Hosseini

Position

Specialist in Social Medicine, Associate Professor

Other areas of specialty/work

Street address

Ganjafrooz Ave, Babol University of Medical Sciences,
Babol

City

Babol

Postal code

4136747176

Phone

+98 11 3219 7667

Fax

+98 11 3219 7667

Email

dr.mouodi@gmail.com

Web page address

mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Simin Mouodi

Position

MD, MPH

Other areas of specialty/work

Street address

Ganjafrooz Avenue, Babol University of Medical
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Fax

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Email

dr.mouodi@gmail.com

Web page address

mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty